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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,287	06/08/2006	Patricia Kwong Phieu Burnell	PB60589USw	4976
23347	7590	11/15/2010	EXAMINER	
GLAXOSMITHKLINE GLOBAL PATENTS FIVE MOORE DR., PO BOX 13398 MAIL STOP: C.2111F RESEARCH TRIANGLE PARK, NC 27709-3398			EVOY, NICHOLAS LANE	
			ART UNIT	PAPER NUMBER
			3768	
			NOTIFICATION DATE	DELIVERY MODE
			11/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/596,287	Applicant(s) BURNELL ET AL.	
	Examiner NICHOLAS L. EVOY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11 and 12 is/are rejected.
- 7) ☒ Claim(s) 4-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/10 has been entered.

Claim Objections

2. Claims 4-10 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *cannot depend from any other multiple dependent claim*. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

3. Claim 11 objected to because of the following informalities: Limitation (b) currently reads: "(b) determining at least one internal physical parameter of the airway defined by the first throat by means of acoustic imaging of the airway defined by the throat;". Limitation (b) would be simplified and clarified if written as "(b) determining at least one internal physical parameter of the airway defined by the first throat by means of acoustic imaging". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 11 recites the limitation "first throat" in lines 10 and 13. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, the term "first throat" is interpreted to mean "first patient's throat".

7. Claim 11 recites the limitation "throat" in line 11. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination the term "throat" is interpreted to mean "first patient's throat".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, in view of Czaja et al., Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105: 1996.

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9. Regarding claims 1 and 11, Sexton teaches a method of improving lung delivery of pharmaceutical aerosols that includes: A method for predicting the tendency of inhaled particles to deposit within a first patient's throat when said particles are inhaled through an airway defined by said first patient's throat, said method comprising selecting at least one internal physical parameter of an airway defined by a throat of at least one other patient (Column 11, Lines 42-50); creating a dataset comprising pre-determined data relating to said at least one internal parameter of the airway defined by the throat of said at least one other patient, said dataset further comprising pre-determined data relating to the tendency of said inhaled particles to deposit within said at least one other patient's throat (Column 12, Lines 8-45 and Column 12, Line 59 - Column 13, Line 12); and determining said at least one internal physical parameter of the airway defined by said first patient's throat (Column 9, Lines 3-15); and matching said at least one internal physical parameter of the airway of the first patient's throat with the dataset comprising pre-determined data relating to the corresponding internal physical parameter for the throat of the at least one other patient (Column 11, Line 63 – Column 12, Line 6 and Column 12, Line 59 – Column 13, Line 12), wherein said matching thereby enables prediction of the tendency for the inhaled particles to deposit within the first patient's throat (Column 12, Lines 8-45 and Column 12, Line 59 - Column 13, Line 12).

10. Sexton does not teach that the method referenced above could be performed using acoustic imaging for image and data acquisition.

Czaja teaches using acoustic impulse reflection imaging to measure physical and geometric characteristics of a human airway (Page 504, Paragraph 1).

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11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sexton and Czaja because the use of acoustic reflectance imaging would render Sexton's method of improving lung delivery of pharmaceutical agents more accurate, low cost, simpler and faster (Czaja: p. 505, Paragraphs 1-2).

12. Regarding Claim 2, Sexton discloses an inhaler that acts as an aerosol drug delivery device during scanning (Column 10, Lines 20-29).

13. Regarding Claim 3, Sexton discloses an inhaler that acts as an aerosol drug delivery device that is capable of delivering multiple types of medicine (Column 12, Lines 7-19).

Claims 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Sexton et al., US Patent Number 6,567,686 B2, taken with Czaja et al., Acoustic Measurement of Subglottic Stenosis; Ann Otol Rhinol Laryngol 105: 1996, in view of Stapleton et al, On the Suitability of e-Turbulence Modeling for Aerosol Dispersion on the Mouth and Throat: A Comparison with Experiment; Journal of Aerosol Science; 2000, Vol. 31, No. 6, pp 739-749.

14. Regarding claim 12, Czaja et al and Sexton et al disclose a method for improving lung delivery of pharmaceutical aerosols and a method for measuring physical and geometric features of an airway using acoustic impulse reflection imaging as referenced above.

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15. Czaja and Sexton do not teach the use of a laboratory model or a specific geometric embodiment for the method. Stapleton et al disclose the use of a laboratory model that is a reconstruction of a previously measured throat (p. 741, Paragraph 7).

Additionally, Stapleton et al disclose that the trachea is often modeled as a nearly cylindrical tube and that its length and diameter are well studied (p. 742, Paragraph 6).

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Czaja et al, Sexton et al and Stapleton et al because all of the inventions are in the field of imaging and modeling the dynamics of air movement in the throat and the construction of three dimensional, cylindrically-based laboratory models is a common method of conducting air movement research (Stapleton, Page 739, Paragraph 1-2).

Response to Arguments

17. Applicant's arguments filed 5/21/10 have been fully considered but they are not persuasive.

18. Regarding Applicant's argument that Sexton does not teach matching at least one predetermined physical parameter from a first patient against a dataset comprising predetermined data relating to the tendency of inhaled particles to deposit within the airway of another person, and that Sexton teaches the opposite approach: using a method of monitoring the role of upper oropharyngeal and laryngeal geometry for the retention and elimination of respiratory drugs when administered by oral inhalation to identify differences between patients:

Sexton discloses that "Block 14 is the final stage where the information from capturing the real-time mobility of oropharyngeal and laryngeal structures during inhalation through an aerosol drug delivery system, the state of aerosol drug delivered, and the database which is obtained from the practice of the method can yield the criteria that can be used to design more efficient aerosol drug delivery to optimize the amount of the particular medicine to be delivered to the specific targets in the lung. This criteria can also be used to develop an aerosol administration procedure that is insensitive to gag and cough reflexes of the body so that aerosolized medicament exiting an aerosol generator effectively escapes filtration and swallowing mechanisms of the oropharynx" (Column 12, Lines 20-33). Clearly, the method of Sexton is disclosed with optimizing drug delivery for a patient based on predetermined data relating to the tendency of inhaled particles to deposit within the airway of another person.

Regarding applicant's argument that Sexton teaches the opposite approach and attempts to identify differences between patients: It would have been obvious to one of ordinary skill in the art at the time of the invention that the method of Sexton and Czaja would be applicable in many types of situations, and that the analytical method is not exclusively retroactive but can be used with reference data to analyze a newly acquired sample from a patient.

19. Regarding applicant's argument that Sexton does not teach the creation of a dataset prior to matching the at least one predetermined physical parameter, but teaches the possible evaluation of differences within the database: As mentioned above, one of ordinary skill in the art would have recognized the ability of the system of

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Sexton to be able to evaluate pre-existing data against itself, as well as against new data generated for comparison.

20. Regarding applicant's argument that there is no teaching in the cited passage, or anywhere else in Sexton, to predict the tendency of particles to deposit within the throat of a patient: Sexton repeatedly discloses collecting and analyzing data on the delivery characteristics and flow rates of an aerosol drug. Specifically, Sexton discloses that "after a review of the imaging, the amount of aerosol drug administered to specific areas in the lung can be determined" (Column 12, Lines 4-6) and that "it is envisioned that coupled with the foregoing method and information obtained thereby, is the use of existing nuclear medicine methodologies for tracing the medicine being dispensed as it passes through one's airways and is deposited at various sites along the administration route. Accordingly, included in the dispense material would be a trace element (e.g. gadolinium, technetium) the presence of which can be monitored in the body through the use of appropriate imaging tools. After collecting the MRI and flow data pertaining to the inhalation and administration of the dispense material containing the trace element, the patient would then be imaged using an appropriate nuclear medicine tool (e.g. gamma camera). Information pertaining to the locations where the material is deposited and to the relative amounts of this material in each location would be generated. Such information, when combined with the dynamic MR image and inhalation flow data, will enhance the understanding of the effectiveness of a particular aerosol delivery system in administering medicine to targeted pulmonary sites as well as the dose size necessary for effective treatment among other things" (Column 12, Line 59 – Column

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13, Line 12). It is clear that Sexton discloses (both explicitly and implicitly) predicting the tendency and location of deposition of particles in the throat.

21. Regarding applicant's argument that Sexton only teaches the creation of the database, and the use of said database for the establishment of design criteria for more efficient drug delivery, and that such a step does not explicitly or implicitly involve predicting the tendency of particles to deposit within a patient's throat: The examiner disagrees with applicant's contention that the step of predicting the tendency of particles to deposit within a patient's throat is not implicit in the disclosure of Sexton (as noted in the arguments above), but even in the case that it is not considered to be implicit, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method of Sexton to make such a prediction based on previously acquired data. Using past data to draw conclusions on the behavior of a system and to make a prediction of future results is a common practice in science and engineering as would be understood by one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS L. EVOY whose telephone number is (571)270-1388. The examiner can normally be reached on M-F 7:30-5:00, Alternating Fridays Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICHOLAS L. EVOY/
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768